

Genentech, Inc.
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Genentech, Inc.

Genentech, Inc.

1 DNA WAY
South San Francisco, CA 94080
(650) 225-1994
Facsimile: (650) 952-9881

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DATE: March 19, 2004

Please deliver the following Communication, Notice Declaring Interference for Interference 105,116 (12 pages) and Notice Declaring Interference for Interference 105,048 (31 pages) to:

NAME: Examiner Christopher Yaen - Group Art 1642
U.S. Patent and Trademark office
Washington, DC 20231

Fax No.: (703) 305-3014

2 of 2

FROM: Wendy M. Lee
Registration No.: 40,378

RE: U.S. Serial No.: 09/705,579
Our Docket No.: P1053R1D1

Number of Pages including this cover sheet - 46

13

Certificate of Facsimile Transmission Under 37 CFR § 1.8

In accordance with CFR § 1.6(d), this correspondence addressed to The Patent and Trademark Office, Washington, DC 20231 is being transmitted to facsimile No. (703) 305-3014.

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If you do not receive all pages, please notify Wendy Lee at (650) 225-1994.

The opinion in support of the decision being entered today is not binding precedent of the Board.

Filed by: Michael P. Tierney
Administrative Patent Judge
Box Interference
Washington, D.C. 20231
Tel: 703-308-9797
Fax: 703-305-0942

Paper 1

Filed
April 22, 2003

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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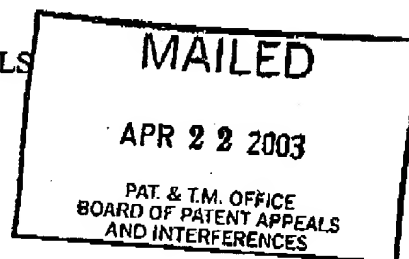
APR 23 2003

GENENTECH, INC.
LEGAL DEPT.

GENENTECH
Junior Party¹

v.

DEPARTMENT OF HEALTH & HUMAN SERVICES, U.S.A.
Junior Party



Patent Interference No. 105,116 (MPT)

NOTICE DECLARING INTERFERENCE
(37 CFR § 1.611)

Part A. Declaration of interference

An interference is declared (35 U.S.C. § 135(a)) between the above-identified parties.

Details of the application(s), patent (if any), reissue application (if any), count(s) and claims designated as corresponding or as not corresponding to the count(s) appear in Parts E and F of this NOTICE DECLARING INTERFERENCE.

¹As the record is unclear as to whether the parties' parent 35 U.S.C. § 120 applications provide a constructive reduction to practice for an embodiment falling within the scope of the count, both parties have been accorded junior party status. Senior party status shall be awarded prior to entering the priority phase of the interference.

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1. Incomplete Record

The official USPTO copy of the 08/472,117 ("117") application is incomplete. For example, the Department of Health and Human Services's (HHS) appeal brief, received December 9, 2002, refers to the entry of an Amendment filed November 21, 2002. Similarly, an examiner interview summary dated December 9, 2002 also indicates that a November 21, 2002 Amendment has been entered. The November 21, 2002 Amendment, however, does not appear in the official copy of the '117 application.

The declaration of this interference is based, in part, upon HHS's December 9, 2002 Appeal Brief, which states that claim 9 in its attached appendix is the only pending claim. To provide a more complete record for the interference, HHS is directed to file and serve a copy of the '117 November 21, 2002 Amendment with the Board by no later than May 5, 2003.

2. Request for Additional Information

As both parties are aware, each party has applications and patents claiming 35 U.S.C. 120 benefit of their earliest filed applications. (See, e.g., Interference No. 104,519, HHS (King) v. Genentech (Slamon) and front page of Hudziak, 6,399,063). To aid in the declaration of the interference, HHS was afforded an opportunity to file a Rule 607 statement identifying the patents and claims that interfere with HHS's pending claim 9. ('117 Application, Paper No. 48). HHS declined this invitation. Lacking HHS's guidance, this interference has been declared with the Genentech (Hudziak) patent and Genentech (Greene) application that appear to best represent the interfering subject matter. This declaration, however, leaves open the question of whether or not there are additional HHS and Genentech patents and applications claiming the same patentable invention as the count.

Genentech is to file and serve a chart depicting the various patent family trees for any applications and patents claiming 35 U.S.C. §120 benefit of Genentech's 07/143,912 (Hudziak) application as well as the 07/126,572 (Greene) application. HHS is to file and serve a similar chart for U.S. Application No. 06/836,414. The charts shall indicate the status of the application/patent (pending, abandoned, expired, unexpired) and the basis upon which 35 U.S.C.

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§120 benefit is claimed (continuation, continuation-in-part, divisional, etc). The Administrative Patent Judge also requests that a copy of any pending and issued claims be filed and served. This submission will aid in the determination of whether any additional applications and patents should be added to the interference. This submission is due by no later than May 5, 2003.

Part B. Judge designated to handle the interference

Administrative Patent Judge Michael P. Tierney has been designated to handle the interference. 37 CFR § 1.610(a).

Part C. Standing order

A Trial Section STANDING ORDER accompanies this NOTICE DECLARING INTERFERENCE. The STANDING ORDER applies to this interference.

Part D. Conference call to set dates

A telephone conference call to set dates for taking action in the interference is scheduled for 11:00 a.m., June 4, 2003 (the call will be initiated from the PTO).

No later than two business days prior to the conference call, each party shall file and serve by facsimile a list of the preliminary motions the party intends to file. See § 17 of the STANDING ORDER.

A copy of a "sample" order setting times for taking action during the preliminary motion phase of the interference accompanies this NOTICE DECLARING INTERFERENCE.

Counsel are encouraged to discuss the order prior to the conference call with the view to coming to some mutual agreement as to dates for taking action. A typical preliminary motion period lasts approximately nine (9) months. Counsel should be prepared to justify any request for a shorter or longer period.

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Part E. The parties involved in this interference are:

Junior Party: Genentech (Greene)

Named inventors: Mark I. Greene, Penn Valley, PA
Jeffrey A. Drebin, Baltimore, MD

Application: U.S. Application No. 09/158,899, filed September 23, 1998

Title: Treatment of Tumors with Monoclonal Antibodies Against
Oncogene Antigens

Assignee: Trustees of the University of Pennsylvania

Accorded Benefit: None

Attorneys: See last page

Address: See last page

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Junior Party: Genentech (Hudziak)

Named inventors: Robert M. Hudziak, Corvallis, OR
H. Michael Shepard, Rancho Santa Fe, CA
Axel Ullrich, Portola Valley, CA
Brian M. Fendly, Half Moon Bay, CA

Patent: U.S. Patent No. 6,399,063, issued June 4, 2002,
based upon U.S. Application No. 09/152,654,
filed September 14, 1998

Title: Monoclonal Antibodies Directed to the HER2 Receptor

Assignee: Genentech, Inc.

Accorded Benefit: None

Attorneys: See last page

Address: See last page

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Junior Party: HHS

Named inventors: C. Richter King, Washington, DC
Matthies H. Kraus, Bethesda, MD
Stuart A. Aaronson, Great Falls, VA

Application: U.S. Application No. 08/472,117, filed June 7, 1995

Title: Human Gene Related to but Distinct from
EGF Receptor Gene

Assignee: Department Human & Health Services, USA

Accorded Benefit: None

Attorneys: See last page

Address: See last page

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Part F. Count and claims of the parties

Count 1

A method according to claim 3 of U.S. Patent No. 6,399,063.

The claims of the parties are:

HHS (King), U.S. Application No. 08/472,117:	9
Genentech (Hudziak), U.S. Patent No. 6,399,063:	1-18
Genentech (Greene), U.S. Application No. 09/158,899:	3-5 and 23-29

The claims of the parties that correspond to Count 1 are:

HHS (King), U.S. Application No. 08/472,117:	9
Genentech (Hudziak), U.S. Patent No. 6,399,063:	1-3, 7-15 and 18
Genentech (Greene), U.S. Application No. 09/158,899:	3-5, 23, 26-27

The claims of the parties that do not correspond to Count 1 are:

HHS (King), U.S. Application No. 08/472,117:	None
Genentech (Hudziak), U.S. Patent No. 6,399,063:	4-6 and 16-17
Genentech (Greene), U.S. Application No. 09/158,899:	24-25 and 28-29

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Part G. Heading to be used on papers

The following heading shall be used on papers filed in the interference. See § 18 of the
STANDING ORDER.

Filed on behalf of [name of party]
By: Name of lead counsel, Esq.
Name of backup counsel, Esq.
Street address
City, State, and Zip-Code
Tel:
Fax:

Paper ____²

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

GENENTECH
Junior Party

v.

DEPARTMENT OF HEALTH & HUMAN SERVICES, U.S.A.
Junior Party

Patent Interference No. 105,116 (MPT)

TITLE OF PAPER

² Leave a blank line because the board assigns the paper number.

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Part H. Summary of dates for taking action

Times for taking action are set out in the following sections of the STANDING ORDER:

- i. § 7: date for identifying lead and backup counsel.
- ii. § 8: date for identifying any real party in interest.
- iii. § 9: date for requesting copies of involved and benefit applications and patents.
- iv. § 17: date for filing list of proposed preliminary motions.
- v. § 19: date for accomplishing certain discovery.
- vi. § 20: date for filing clean copy of claims.
- vii. § 21: date for filing clean copy of claims in cases with drawings and/or claims containing a means plus function limitation.
- viii. § 23: dates for filing oppositions to Rule 635 miscellaneous motions and dates for filing replies to oppositions.
- ix. § 33: date for objecting to admissibility of evidence.
- x. § 34: date for serving supplemental affidavits or evidence to respond to objection to admissibility of evidence.
- xi. § 35: dates when cross-examination can take place.
- xii. § 45: dates for taking action with respect to settlement discussions

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Part I. Order form for requesting file copies

FILE COPY REQUEST

Interference No. 105,116

A copy of Part E of this NOTICE DECLARING INTERFERENCE should be attached to this FILE COPY REQUEST, with a circle by hand around the patents and applications for which a copy of a file wrapper is desired.

To facilitate processing of this FILE COPY REQUEST, the following information should be included:

1. Charge fees to USPO Deposit Account No. _____
2. Complete address, including street, city, state, zip code and telephone number (do not list a Post Office box inasmuch as file copies are sent via commercial overnight courier).

Telephone, including area code: _____

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Part J. Signature of administrative patent judge


MICHAEL P. TIERNEY
Administrative Patent Judge

Date: 4/22/03
Arlington, VA

Enc:³

Copy of STANDING ORDER

Copy of order used for setting times for taking action in the preliminary motion phase of the interference

Copy of order used for setting times for taking action in the testimony and briefing phases of the interference

Copy of HHS Appeal Brief dated December 9, 2002, with attached appendix containing pending claim 9.

Copy of Genentech (Hudziak), U.S. Patent No. 6,399,063.

Copy of pending claims of Genentech (Greene), U.S. Application No. 09/158,899.

³No Rule 609(b) or Form PTO-850 is enclosed.

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cc (via Facsimile with enclosures sent via Federal Express):

Attorney for GENENTECH:

Steven B. Kelber, Esq.
PIPER, MARBURY, RUDNICK & WOLFE LLP
1200 Nineteenth St., N.W.
Washington, D.C. 20036-2412

Tel.: 202-861-6675
Fax: 202-223-2085

Wendy M. Lee
GENENTECH, INC.
1 DNA Way
South San Francisco, CA 94080

Tel: 650-225-1994
Fax: 650-952-9881

Attorney for HHS:

Robert A. Hodges
NEEDLE & ROSENBERG, P.C.
127 Peachtree Street, NE
Suite 1200, The Candler Building
Atlanta, GA 30303-1811

Tel: 404-688-0770
Fax: 404-688-9880